



**Investor Update** 

#### **Company Profile**

- Clinical-stage specialty pharmaceutical (ASX: QRX)
  - Core focus: commercialisation of new products/treatment paradigms for pain management and chronic central nervous system (CNS) disorders
- Pipeline of late and early stage candidates
  - Development strategy: re-engineer known drugs to enhance and expand their clinical utility and commercial value
- Strong IP portfolio with international protection
  - 6 issued and 6 patents pending (Australia, EU, Japan, & Canada)
- Clinical Trials
  - Q8003IR (Acute Pain) to begin Phase 3 Trials late-2007
  - Q8011CR (Chronic Pain) to complete Phase 1 Trials 2008
  - T9001 (Dystonia) to begin Phase 2 Trials in 2008
- Experienced Board and executive team
- Market capitalisation of \$112 million on 24 Oct.



### **Competitive Advantages**

- Know-how to build and sustain shareholder value; proven track record of Board and management team
- Focused business strategy targeting specialist-driven sectors with welldefined needs
- Development strategy to harness unique properties of patented technologies and reengineer known drugs to develop new therapies with enhanced clinical benefits
  - Dual Opioid Platform (Pain Management) and Torsin Platform (CNS Disorders)
  - Abbreviated R&D paths, streamlined regulatory approvals, reduced risk of failure and renewed market value
- Resources in place to fund upcoming clinical program
  - On track and on budget with clinical trials projections

# **Product Pipeline**

PRODUCT/PROGRAM PAIN MANAGEMENT	RESEARCH	PRE-CLINICAL	PHASE I	PHASE II	PHASE III
Q8003IR Q8011CR					
CNS					
T9001 (Dystonia)					
T9001 (Parkinson's)					
VENOMICS					
Q8010					
Q8008					



## **Pain Therapy Market**

- Global pain market estimated at US\$50 billion, forecast to reach US\$75 billion by 2010
  - Worldwide opioid market US\$9 billion in 2005
  - US market US\$6.6 billion;13% annual growth from 2001 to 2005
- Limited product innovation to date; reliance on older therapies
  - Opioids are the "gold standard" in treating moderate to severe pain
- Clear need for improved drugs with fewer side effects and risk factors
  - Respiratory depression, constipation, nausea, vomiting, somnolence

#### The Opportunity Equation

- <u>Problem</u>: Side effects and associated risks limit clinical value of "gold standard" opioid pain drugs
- Need: Improved pain relief with fewer side effects and risk factors
- Solution: Engineer first-in-class drug which harnesses therapeutic potential of opioids with lower risk profiles
  - Dual-opioid platform technology
    - Offers greater clinical benefit vs. existing opioid pain therapies
  - Achieve pain relief at materially lower doses of active ingredient (improved safety)
  - Significant reduction of side effects (i.e. respiratory depression, constipation, nausea, vomiting, somnolence) and potential for abuse
  - Closely monitored and regulated market
    - Reinforces sustainable competitive advantage



#### **Product Overview**



### **Dual Opioid Platform Technology**

- Synergistically combines existing opioids to enhance clinical value/use
  - Lower dosage formulation (i.e. sub-analgesic doses)
  - Pain relief with fewer side effects and associated risks
  - Supported by a number of clinical studies, including recent post-spinal surgery study (Blumenthal *et al*)
- Two complementary oxycodone-morphine products, positioned to:
  - Cover broad range of pain states/types
    - Q8003IR: immediate release dual opioid for acute pain
    - Q8011CR: controlled release dual opioid for chronic pain
  - Reduced development costs and abbreviated regulatory processes
  - Minimise generic substitution
    - Greater market value for direct commercialisation in US and potential for partnerships abroad

### Q8003IR – Immediate Release Dual Opioid

- Clinical data demonstrate that oxycodone-morphine combination delivers:
  - reduction in opiate use (lower dosage)
  - Significantly lower pain scores (greater relief)
  - Lower incidence of adverse effects, notably nausea and vomiting (improved benefits)
- QRxPharma's lead product candidate
  - Primary focus on acute pain; secondary market chronic pain
- Milestone timeline to market launch
  - November 2007: Phase 2/3 study for acute pain in post-surgical bunionectomy patients
  - Late 2007: Phase 3 to begin enrolling patients
  - 2008: Completion of first Phase 3 and NDA manufacturing batches (stability assessment data)
  - 2009: Completion of additional Phase 3 studies, long-term safety, and NDA filing
  - 2010: NDA approval, US launch, other markets
- On track to commence Phase 3 trials before end of 2007



#### **Recent Progress Towards Phase 3 Trials**

- Leverage in-house regulatory, manufacturing and development know-how to achieve timetable outlined in Prospectus
- Since the conclusion of FY07, significant progress made towards initiating Q8003IR Phase 3 trials in late-2007
  - Focus on acute post-surgical pain
  - Completion of product manufacturing
  - Finalisation of clinical trial protocols
  - Selection of Clinical Research Organisation (CRO) and trial sites
  - IRB approvals in place



### **Q8011CR – Controlled Release Dual Opioid**

- Targeting chronic pain market
  - Strong market need for controlled release opioid
  - Complementary to Q8003IR
  - Inherent abuse-deterrent technology
- Milestones and clinical development timeline
  - Mid-2008: Phase 1 clinical trials complete
  - Late-2008: Targeted initiation of Phase 2 trials
- Recent progress on production of clinical trial materials – on schedule to meet Phase 1 timeline



### **Dual Opioid "Go-to-Market" Strategy**

- Initially targeting the US market over 70% of current global opioid market
- Recruitment of specialty pharma sales force in US

  One-third of market can be covered by approximately 120-150 salespeople

  Targeting specialised (pain) physicians, pain clinics and high prescribing MDs

  Explore strategic partnerships to expand market penetration
- Precise "go-to-market" strategy based on product-oriented science and large, well-defined market
- Relationship with Sigma Pharmaceuticals in Australia
- Licensing opportunities in Europe and Rest of World



#### **CNS Market**

- With aggregate value of \$86 billion (2005), the CNS market is the largest of all therapeutic areas
- No drugs yet available to treat Parkinson's and dystonia at causative level
- Significant advances as to molecular and cellular biology of neurodegenerative disorders point to potential of new therapies
  - Recent discovery that DYT-1 gene and the protein it encodes -- Torsin -- is critical for normal cellular brain function
  - Role of Torsin prevents protein misfolding associated with the cause of movement disorders
  - Preclinical studies demonstrated that an existing drug activates the Torsin system,
     prevents protein mutations and ameliorates movement disorders
  - Preliminary anecdotal clinical observations with patients suffering from dystonia also support such findings



#### **T9001 CNS Product Candidate**

- R&D alliances with world-leading Caldwell Lab at University of Alabama
  - Research supported by American Parkinson's Disease Association, the Dystonia Medical Research Foundation, and the Michael J. Fox Foundation
  - Grant applications recently filed to advance studies in Parkinson's disease and dystonia
  - Exclusive license to molecules and IP portfolio of Torsin inventions at UA
- T9001 for movement disorders (Parkinson's and dystonia)
  - Specific antibiotic modulates key Torsin-related pathways
  - Clinical development timeline and milestones
    - Lead drug candidates selected process underway; re-engineering known drugs
    - Currently sourcing manufacturing
    - Negotiating to initiate pilot investigator Phase 2 clinical trial in 2008



### **Business Development**

- Ongoing licensing and partnering activities
- Actively pursuing grant opportunities to partially fund product development
- Next late-stage CNS drug candidate being analysed
- Other early stage pipeline compounds include:

Q8020TD (transdermal fentanyl/oxycodone patch)

Q8008 (recombinant peptide)

Q8010 (pro-coagulant)

Q70050 (venomics research program)

Government grants for venomics project conducted with University of Queensland – A\$0.8 million over 3 years



### **Strong and Appropriate Resources**

- Requisite financial, scientific and human capital
- QRxPharma draws on a depth of relevant experience in:
  - Integration of academic, scientific and commercial knowledge into targeted specialist-driven products
  - Product R&D for both public and privately-held life sciences companies
  - Product commercialisation
  - Regulatory approval processes
  - Managing and financing publicly traded companies
- Access to an extensive network of industry experts
- Highly-credentialed Science Advisory Board (SAB) lead by Dr.
   Solomon Snyder and bolstered by recent appointments of Dr. Lester
   Crawford (former head of FDA) and Dr. Gavril Pasternak



#### **QRxPharma:** Poised to Execute

- Clinical-stage specialty pharmaceutical company
- Focus on pain management and CNS disorders
  - Dual opioid technology platform: delivers pain relief with lower dosage and fewer side effects
  - Torsin technology: correct misfolded proteins and reverse progressive effects
- Drug development approach (re-engineer marketed drugs to enhance or expand clinical utility and commercial value)
  - Shorten transition from bench to market
- Early and late stage pipeline; clinical trial timelines proceeding to plan
- Resources in place for Q8003IR Phase 3 trials and NDA filing
- Management team ready to deliver company potential and drive shareholder value



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